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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,061	06/20/2003	Cesar Z. Lina	P-3460(CON)	5656

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EXAMINER

HAND, MELANIE JO

ART UNIT PAPER NUMBER

3761

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,061

Applicant(s)

LINA ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/20/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Priority

Acknowledgement is made of Applicant's claim for priority for this application as a continuation of Application No. 09/545,339, filed April 7, 2000.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 20, 2003 was filed simultaneously with Application No. 10/600,061. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 1, 8, 10 and 11 are objected to because of the following informalities:

With respect to **Claims 1 and 8**: Because Claim 8 depends upon Claim 1 and therefore contains all of its limitations, the phrase in Claim 8, "wherein said porous pad is formed by spraying a nontoxic chemical substance" is inconsistent with the following phrase in Claim 1, "having at least a partial outer surface and an inner body". Prior art

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overwhelmingly teaches that a substance sprayed out from a container by means of a nozzle or other similar device is ejected in one uniform state. Both the Applicant and the prior art imply in their disclosures that any device having a partial outer surface and an inner body also have two distinct states (e.g. foam with solid porous crust layer) existing simultaneously. Further explanation and/or modification are required to allow Claim 11 to be consistent with Claim 1.

With respect to **Claim 10**: The precise meaning of “material modifications to enhance biocompatibility” in line 4 of Claim 10 is unclear. The material modifications are interpreted here as being the relatively smaller first pore size when compared to second pore size to prevent tissue migration into the pores of the outer surface. This interpretation is based on the reference to the reason for the limit on the first pore size stated in the specification on page 14, lines 9,10 and the language set forth in Claim 1, “having pores of a first average size to enhance biocompatibility”.

With respect to **Claim 11**: Because this claim depends upon Claim 10 and therefore contains all of its limitations, the language of Claim 11, “wherein said pad is formed by spraying a nontoxic chemical substance” is inconsistent with the following language in Claim 10, “having at least a partial outer surface and an inner body”. The prior art teaches as a whole that a substance sprayed out from a container by means of a nozzle or other similar device is ejected in one uniform state. Both the Applicant and the prior art imply in their disclosures that any device having a partial outer surface and an inner

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body also have two distinct states (e.g. foam with solid porous crust layer) existing simultaneously. Further explanation and/or modification are required to allow Claim 11 to be consistent with Claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 9, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of Shioya et al (U.S. Patent No. 4,997,425).

With respect to **Claim 1**: Hunt teaches a porous pad 102 (Fig. 1) that is permeable to liquids and that is held in place by a surgical drape 701 with adhesive providing a seal

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around said pad and wound (Col. 5, lines 26-29). Hunt also teaches a vacuum canister 100 for collecting drainage fluid that is sucked from the wound via a suction pump 6 and connected to the porous pad through a drainage tube 101 (Fig. 1). Hunt does not teach an outer surface with pores of a first size contacting the wound or a pad with an inner body with pores of a second average size. Shioya teaches a dressing with an outer surface layer 5 superimposed on an inner sponge layer 3 (Fig. 1). The outer layer 5 contains pores of an average pore size that is less than the average pore size of pores in the inner sponge layer 3. Shioya teaches that the first average size pore is no more than 20 microns to prevent foreign bacteria from invading the wound, and that the second size pore in the outer layer 5 is in the range of 20 to 500 microns because a pore size below 20 microns results in poor development of tissue and insufficient absorption of exudate, both of which are critical as the outer layer 5 is contacting the wound surface, and a pore size larger than 500 microns may result in inadequate adhesiveness to the wound surface to allow the exudates to remain (Col. 4, lines 11-18). Therefore it would be obvious to modify the dressing of Hunt to include the second pore size in its wound-contacting surface to foster proper development of new healthy tissue and ensure appropriate adhesiveness to the wound surface as taught by Shioya.

With respect to **Claim 2**: Hunt teaches that a hole is cut through all layers of the surgical drape 701 holding the dressing in place to accommodate the drainage tube (Col. 5, lines 30-33).

With respect to **Claim 3**: By virtue of having pores in a dressing that is drained via negative pressure from a suction pump, the pores of a second average size in the dressing taught by Hunt and modified by Shioya are considered here to be vacuum-compatible.

With respect to **Claim 4**: Hunt teaches that the dressing is a pad of polyurethane foam (Col. 5, lines 49-51).

With respect to **Claim 5**: Shioya teaches pores of a first average size in the outer layer 5 that are no larger than 20 microns in diameter (Col. 10, lines 63-65).

With respect to **Claim 6**: Hunt teaches that the surgical drape is comprised of polyurethane film (Col. 8, lines 27-28).

With respect to **Claim 7**: Shioya teaches the addition of an antimicrobial agent to the porous wound dressing (Col. 6, line 65-Col. 7, line 2).

With respect to **Claim 9**: Shioya teaches that the outer surface layer 5 can be added to a sponge layer 3 both comprised of a poly- α -amino acid solution embedded with a reinforcing material such as polyurethane (Col. 6, lines 12-18). The two layers 3 and 5 are constructed by following a process comprising the use of liquid poly- α -amino acid in one of its steps (Col. 5, lines 54-56). Shioya teaches that the poly- α -amino acids readily

polymerize, are able to be freeze-dried under vacuum, and are of good workability, and therefore are suitable for molding in processes such as the one described to form the outer layer 5 (Col. 5, lines 1-4). Therefore it would be obvious to modify the polyurethane porous pad of Hunt by adding an outer layer with smaller pores than those of the porous pad using the liquid poly- α -amino acid and process taught by Shioya.

With respect to **Claim 10**: Hunt teaches a porous pad 102 (Fig. 1) that is permeable to liquids and that is held in place by a dressing providing a substantially airtight seal around said pad and wound (Col. 6, lines 17-19). Hunt also teaches a vacuum canister 100 for collecting drainage fluid that is sucked from the wound via a suction pump 6 and connected to the porous pad through a drainage tube 101 (Fig. 1). Hunt does not teach an outer surface with pores of a first size contacting the wound or a pad with an inner body with pores of a second average size. Shioya teaches a dressing with an outer surface layer 5 superimposed on an inner sponge layer 3 (Fig. 1). The outer layer 5 contains pores of an average pore size that is less than the average pore size of pores in the inner sponge layer 3. Shioya teaches that the first average size pore is no more than 20 microns to prevent foreign bacteria from invading the wound, and that the second size pore in the outer layer 5 is in the range of 20 to 500 microns because a pore size below 20 microns results in poor development of tissue and insufficient absorption of exudate, both of which are critical as the outer layer 5 is contacting the wound surface, and a pore size larger than 500 microns may result in inadequate adhesiveness to the wound surface to allow the exudates to remain (Col. 4, lines 11-

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18). Therefore it would be obvious to modify the dressing of Hunt to include the second pore size in its wound-contacting surface to foster proper development of new healthy tissue and ensure appropriate adhesiveness to the wound surface as taught by Shioya.

With respect to **Claims 12 and 13**: Shioya teaches that the outer and sponge layers are continuously formed with no boundary therebetween (Col. 10, lines 48-49). It would be obvious to modify the porous pad of Hunt to create a porous dressing as taught by Shioya wherein the sponge layer is attached to the outer layer contacting the wound to enable quick and painless removal of the dressing for replacement without further damaging healthy tissue surrounding the wound site.

With respect to **Claims 14 and 15**: Hunt teaches that the seal around the wound site is substantially airtight (Col. 6, line 18).

With respect to **Claim 16**: Hunt teaches one filter interposed between a suction pump and a vacuum canister (Col. 6, lines 57-59).

With respect to **Claim 17**: Hunt teaches that a suction pump is adapted to draw liquid from a sealed porous pad through a drainage conduit and into a vacuum canister (Col. 6, lines 23-25).

Claims 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al (U.S. Patent No. 6,142,982) in view of Shioya et al (U.S. Patent No. 4,997,425) as applied to claims 1-7, 9, 10 and 12-17 above, and further in view of Coffee (U.S. Patent No. 6,252,129)

With respect to **Claims 8 and 11**: Hunt in view of Shioya does not teach a foam dressing that may be released from a spray nozzle and deposited directly into the wound cavity, subsequently conforming to the shape of the wound cavity. Coffee teaches spraying a nontoxic polymeric flexible foam deposit into a wound to form a cavity wound dressing, with the dressing conforming to the contours of a cavity wound (Col. 13, lines 52-55). It would be obvious to further modify the wound dressing taught by Hunt and modified by Shioya to be able to be sprayed directly onto the wound wherein the dressing is a foam material that conforms to the shape of the wound as these spray devices are known, as taught by Coffee (Col. 1, lines 14-17).

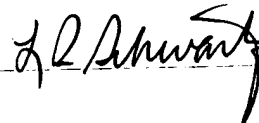
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on 571-272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH



Larry I. Schwartz
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Group 3700